IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GAYATHRI MURTHY, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	)))))))))	CASE NO. 4:11-cv-00105-KPE JURY TRIAL DEMANDED

DEFENDANT'S REPLY BRIEF IN FURTHER SUPPORT OF
MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

Plaintiff's complaint centers on the adequacy of warnings accompanying an FDA-approved prescription drug (Humira) prescribed and administered for an FDA-approved indication (the treatment of rheumatoid arthritis). Thus, Plaintiff's products liability claims fit squarely within the ambit of, and are barred by, the plain language of Tex. Civ. Proc. & Rem. Code § 82.007 ("Section 82.007"). Faced with this on-point and dispositive statutory authority requiring dismissal, Plaintiff opposes Abbott's motion by offering the following equally unavailing theories.

First, Plaintiff attempts to avoid the import of Section 82.007 by "questioning" (without citation to a single authority) whether the Section applies to an FDA-approved drug received in connection with an FDA-monitored clinical trial, and by suggesting that there may be non-enumerated "exceptions" to the Section's broad statutory prohibition against liability. These unsupported interpretive gymnastics are in direct contradiction to Texas canons of statutory construction and cannot be used to avoid dismissal.

Plaintiff next attempts to fit her case within proposed exceptions to the "learned intermediary" doctrine. These "exceptions" include (i) a narrow "direct-to-consumer"

advertising exception, supported by one outlier Texas appellate court opinion with questionable applicability to the facts of this case and (ii) Plaintiff's unilateral declaration (again supported by no authority) that the learned intermediary doctrine does not apply if the physician-intermediary also serves as a clinical investigator. These purported exceptions are neither binding on this Court nor apposite to this case.

Plaintiff fares no better when trying to oppose the dismissal of her breach of contract claim. The contract claim is likewise ripe for dismissal because she has failed to allege facts showing that Abbott actually breached the agreement in question. In particular, Plaintiff neither alleges that she demanded payment under the agreement, nor that Abbott denied such demand, nor that Abbott had determined that she sustained any injuries directly caused by the clinical trial (a prerequisite for payment under the plain language of the agreement).

Finally, rather than address Abbott's arguments on the merits, Plaintiff devotes much of her brief to baseless and misleading suggestions that Abbott's attorneys breached the duty of candor owed the Court and unsupportable arguments that the pleading requirements recognized by *Twombly* and *Iqbal* do not apply to her case. These claims and characterizations are inaccurate and cannot be invoked to withstand summary dismissal.

I. Plaintiff Has Not Alleged Facts Necessary to Rebut Section 82.007's Presumption That Humira's Warnings Were Adequate as a Matter of Law.

Section 82.007(a)'s presumption that Humira's warnings were adequate as a matter of law applies to and requires dismissal of all Plaintiff's products liability claims, including breach of warranty, strict liability, and negligence.[1] Plaintiff may only rebut the presumption by

[1] The § 82.007(a) presumption applies to all "products liability action[s]," which include actions "based in . . . strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." *Id.* at § 82.001(2); *see also Thurston v. Merck and Co. Inc.*, No. 10-20485, 2011 WL 817520, at *1 (5th Cir. Mar. 9, 2011) (affirming Rule 12(b)(6) dismissal of failure-to-warn claims under § 82.007 where the complaint did not plead facts sufficient to meet any of the statutory exceptions); Mot. at 15. Plaintiff alleges that Abbott ignores "misrepresentation allegations," including the allegation that Dr. Popovich, acting as

alleging sufficient facts showing that her claims fall within one of several narrowly-drawn exceptions under Section 82.007(b). The Court should reject Plaintiff's unconvincing attempts to fit the facts of her case into one of these exceptions.

For example, Plaintiff claims that, because she received an FDA-approved drug for an FDA-approved indication while she was also involved in clinical trial, she meets one of these exceptions because her use was for "an indication not approved by the [FDA]." (*See* Opp. at 8-9) Plaintiff does not (and cannot) provide any citation or authority for this bizarre claim that the use of an FDA-approved drug during an FDA-monitored clinical trial is tantamount to "an indication not approved by the FDA."

Plaintiff also raises the narrow exception applying where a defendant "withheld from or misrepresented to the [FDA]" material information. This "fraud-on-the-FDA" exception, however, is no longer viable under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).[2] Moreover, Plaintiff's amended complaint is utterly devoid of any factual allegations that would support such a claim. And Plaintiff's prediction that, "once evidence is developed during discovery," she "will be able to show that Abbott has withheld evidence from the FDA" (Opp. at 10-11), does not meet the pleading standards recognized in *Iqbal* and its progeny. As the Supreme Court explained, "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Ashcroft v. Iqbal*, ---U.S. ---, 129 S.Ct. 1937, 1950

Abbott's clinical investigator and agent," misrepresented the safety of Humira. This is incorrect. Abbott addressed Plaintiff's allegations of agency in the context of the application of the learned intermediary doctrine. (*See* Mot. at 16-17). Moreover, the plain language of Section 82.007 makes clear that the liability bar applies to misrepresentation claims as well. (*See* § 82.001(2)). And, in any event, the Complaint does not allege a cause of action for misrepresentation.

[2] Plaintiff's argument that if the "fraud-on-the-FDA" exception is unconstitutional then the whole statute is unconstitutional (*see* Opp. at 10-11) is contradicted by authorities directly on point. *See* Tex. Gov. Code § 311.032(c) (provisions of "a statute that does not contain a provision for severability or nonseverability . . . are severable."); *Ledbetter v. Merck & Co., Inc.*, Nos. 2005-59499, 2005-58543, 2007 WL 1181991 (Tex. Dist. Apr. 19, 2007) (citing Tex. Gov. Code § 311.032(c) and concluding that Section 82.007 "is severable.").

(2009).[3]

Finally, Plaintiff's unsupported suggestion that the list of exceptions to Section 82.007's liability bar "seems to be . . . non-exclusive" (Opp. at 10) is insufficient to support the introduction of a new exception—particularly where, as here, the statutory exceptions that were adopted by the legislature are specifically enumerated within the statute. "When s***pecific exclusions or exceptions*** to a statute are stated by the Legislature, the intent is usually clear that ***no other shall apply***." *McCalla v. State Farm Mut. Ins. Co.*, 704 S.W.2d 518, 519 (Tex. App. 1986) (emphasis added) (citing *State v. Richards*, 301 S.W.2d 597 (Tex. 1957)).

Plaintiff's corollary argument that Section 82.007(a) is inapplicable because "not *all*" of the information given to her may have been FDA-approved fares no better because it is based solely on *dicta* in a non-binding state appellate court opinion. (*See* Opp. at 9.) Plaintiff quotes from *Centocor, Inc. v. Hamilton*—a "learned intermediary" case, involving a consumer-patient video that has nothing to do with the interpretation or application of Section 82.007. Indeed, the *Centocor* opinion makes clear that ***Section 82.007 had no application in that case***. *See* 310 S.W.3d 476, 505 n.17 (Tex. App. 2010) (Section 82.007 became effective after the *Centocor* suit was filed and was not applied retroactively). In contrast, Section 82.007 does apply to the instant case.

Moreover, *Centocor's* suggestion, in *dicta*, that there may be an exception to Section 82.007 where there is direct-to-consumer advertising finds no support in the wording of the statute or the legislative history. As the Texas Supreme Court has recognized, "[t]he State's public policy is reflected in its statutes." *Fairfield Ins. Co. v. Stephens Martin Paving, LP*, 246 S.W.3d 653, 655 (Tex. 2008) (internal quotations and citation omitted). And the policy of

[3] Indeed, the "expense of discovery" was one of the drivers behind the Supreme Court's reasoning in *Twombly*. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-60 (2007).

Section 82.007(a) is clear: drug manufacturers in failure-to-warn cases "***would not be liable*** if the warnings or instructions that accompanied the medicine were those required by the [FDA]."[4] Section 82.007 was enacted in 2003, long after the advent of the "direct-to-consumer advertising in the 1980s" (*see Centocor*, 310 S.W.3d at 506) and several years after the New Jersey Supreme Court created a direct-to-consumer advertising exception under that state's law in response to the prevalence of such advertising. *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1247 (N.J. 1999). The Texas legislature enacted Section 82.007 in this context but declined to include a direct-to-consumer advertising exception. *See* Section 82.007(b).

II. The Learned Intermediary Doctrine Provides an Additional Basis for Dismissing Plaintiff's Product Liability Claims.

The learned intermediary doctrine applies to this case and provides an additional basis for dismissing Plaintiff's failure-to-warn causes of action.[5] *See* Mot. § III. Plaintiff argues that the doctrine does not apply under the direct-to-consumer marketing exception purportedly adopted in *Centocor* and because Dr. Popovich was allegedly Abbott's agent. However, the *Centocor* decision is neither binding on this Court nor applicable to the circumstances at issue here. And plaintiff's attempt to carve out an investigator-exception to the doctrine should likewise be rejected.

A. *Centocor* Is Neither Binding on This Court Nor Applicable to This Case.

As an initial matter, *Centocor* (which is on appeal to the Texas Supreme Court) is not binding on and should not be followed by this Court because it is at odds with settled Texas law.

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[4] *See* House Research Org., Bill Analysis, Tex. H.B. 4, 78th Leg., R.S. (2003) at 35 (emphasis added) (App. Tab. 7); *see also* Civil Practices Comm., Bill Analysis, Tex. C.S.H.B. 4, 78th Leg., R.S. (2003) at 1, 3 (explaining that Section 82.007 was passed in an "environment of excessive litigation" as part of "a comprehensive civil justice reform bill intended to address and correct problems that currently impair the fairness and efficiency of our court system," and was intended to "clarify[] the application and scope of the ***protections*** for product manufacturers who comply with government standards relating to their products.") (App. Tab. 8).

[5] Because Plaintiff's action is based on a failure to adequately warn, the learned intermediary doctrine applies to her strict liability, negligence and breach of warranty claims. *See Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008); *see also* Mot. at 17.

In purporting to establish such an exception, the *Centocor* court relied exclusively on non-Texas authorities, *see* 310 S.W.3d at 503-04; Mot. at 19, and is not binding on this Court. *See, e.g., Packard v. OCA, Inc.*, 624 F.3d 726, 729 (5th Cir. 2010) ("decisions of Texas intermediate appellate courts may provide guidance, ***but are not controlling***" in a federal case) (emphasis added).[6]

Moreover, the reasoning on which the *Centocor* court relied in creating this exception is inapplicable here. The *Centocor* court recognized the exception where direct-to-consumer advertising "fraudulently touts the drug's efficacy while failing to warn of the risks" 310 S.W.3d at 499. There are no allegations of fraudulent touting here. Even the most charitable reading of the Amended Complaint ("Am. Compl.") is simply that the Abbott video "paints a rosy picture" of therapy with Humira, while conceding that Abbott's label expressly discloses that lymphomas in clinical trials were "approximately 5-fold higher than expected in the general population." *Compare* Am. Compl. ¶ 17 to Am. Compl. ¶¶ 20-21. The allegations of the Amended Complaint fall far short of even the limited exception purportedly recognized in *Centocor*.[7]

B. Dr. Popovich's Status as a Clinical Investigator Does Not Bar Application of the Learned Intermediary Doctrine.

Plaintiff's assertion that Dr. Popovich's status as a clinical investigator for Abbott "*ipso facto*" bars the application of the learned intermediary doctrine (*see* Opp. at 15) also fails.

[6] Every pre-*Centocor* federal decision applying Texas law had rejected claims that a direct-to-consumer exception applies to the learned intermediary doctrine and predicted that the Texas Supreme Court would not recognize such an exception. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 708 (E.D. Tex. 1997) (dissemination of patient informational materials "should not serve as a basis to displace or create exceptions to the learned intermediary doctrine") (collecting cases); *aff'd*, 165 F.3d 374, 379 (5th Cir. 1999) ("as long as a physician-patient relationship exists, the learned intermediary doctrine applies."); *Ebel*, 536 F. Supp. 2d at 781-82 ("Plaintiff provided no evidence of Defendant's mass media distribution of information" and "this Court does not predict that the Texas Supreme Court would adopt that exception to the learned intermediary doctrine.").

[7] Tellingly, in their brief to the Texas Supreme Court, plaintiffs-respondents distanced themselves from the appellate court's flawed reasoning, claiming that the "new law is unnecessary to upholding the judgment . . . ." *See* Respt's Response to Pet. for Review, at 8, filed on Jan. 5, 2011, *Centocor, Inc. v. Hamilton*, No. 10-0223 (Tex.) (App. Tab 6); *see also id.* at 9 n.34 (suggesting the Texas Supreme Court "express[] no opinion about the reasoning of the court of appeals.").

Contrary to Plaintiff's proclamation that this issue "is not addressed in any legal opinion" (Opp. at 14), the Supreme Court of Ohio[8] addressed precisely this question over twenty years ago and, after thoughtful analysis, concluded that the clinical investigator-doctor "***was*** a learned intermediary." *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 879 (Ohio 1991).[9] The Court should reject Plaintiff's unsupported argument that Dr. Popovich's position as clinical investigator precludes application of the learned intermediary doctrine.

Moreover, Plaintiff has failed to allege facts sufficient to support the finding of agency that would be required to make out a claim under *Iqbal*.[10] Plaintiff's bare assertions of agency are not a substitute for factual allegations showing that Dr. Popovich acted as Abbott's agent. *Iqbal*, 129 S.Ct. at 1950 (legal conclusions are not assumed to be true, "they must be supported by factual allegations"). ***"Agency is a legal relationship***" that "is ***never presumed***." *Karl Rove & Co. v. Thornburgh*, 39 F.3d 1273, 1296 (5th Cir. 1994) (citations omitted) (emphasis added). Plaintiff repeatedly asserts that Dr. Popovich was Abbott's agent, but fails to plead sufficient facts to support either of the two essential elements of agency: the authorization to act and control of the action. *See Reliant Energy Servs., Inc. v. Cotton Valley Compression, LLC*, --- S.W.3d---, No. 01-08-00148-CV, 2011 WL 480982, at *12 (Tex. App. Feb. 10, 2011).

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[8] Until *Centocor*, the learned intermediary doctrine was the same under Texas and Ohio law. *Compare Tracy*, 569 N.E.2d at 878 (the manufacturer "discharge[s] its duty to warn if the manufacturer adequately warns the physician") *with Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010) ("so long as the drug manufacturer properly warns a prescribing physician . . . the manufacturer is excused from warning each patient who receives the drug.") (citation omitted).

[9] At least one other court has applied the learned intermediary doctrine to dismiss claims when physicians were clinical investigators. *See Kernke v. The Menninger Clinic, Inc.*, 173 F. Supp. 1117, 1122, 1121-24 (D. Kan. 2001) (rejecting the argument "that the learned intermediary doctrine should not apply in this case" and granting summary judgment for defendants on all claims).

[10] Plaintiff's argument that because Abbott is defending other Humira-related cases "the *rationale* of *Twombly*/*Izbal* [sic] is not present in this case" and therefore the pleading standard of these cases ***does not apply*** to this case (Opp. at 3-5) is without merit. *Ashcroft v. Iqbal*, --- U.S. ---, 129 S.Ct. 1937, 1953 (2009) ("Our decision in *Twombly* expounded the pleading standard *for all civil actions* . . . .") (internal quotation marks omitted) (emphasis added). Further, contrary to Plaintiff's claim, dismissal here does not hinge solely on whether the Complaint has alleged "enough facts." *See* Opp. at 1 n.1. The application of Section 82.007 and the learned intermediary doctrine provide independent bases for dismissal. *See* Mot. at 14-20; *supra* Sec. II.

Plaintiff's assertion that Dr. Popovich was Abbott's "paid clinical investigator" (Opp. at 15)—the ***only*** factual allegation Plaintiff makes that conceivably relates to agency—falls far short of the required showing of right of control. Absent allegations that Abbott had the right to control Dr. Popovich, the agency claim fails as a matter of law. *See Hildebrandt v. Indianapolis Life Ins. Co.*, 2009 WL 877713, No. 3:08-CV-1815-B, at *11 n.8 (N.D. Tex. Mar. 31, 2009) ("absent allegations of control, the pleadings are insufficient.").[11] Finally, Plaintiff's suggestion that discovery may reveal evidence of agency (*see* Opp. at 15) does not satisfy the *Iqbal* standard.

III. Plaintiff's Breach of Contract Claim Is Factually Insufficient.

Plaintiff's breach of contract claim should be dismissed because she fails to allege sufficient facts to make out a claim on which relief can be granted. To make out a breach of contract claim, Plaintiff must allege, *inter alia*, that Abbott breached the agreement. *Bridgmon v. Array Systems Corp.*, 325 F.3d 572, 577 (5th Cir.2003) (citing *Frost Nat'l Bank v. Burge*, 29 S.W.3d 580, 593 (Tex. Ct. App. 2000). Plaintiff alleges that Abbott is contractually bound to pay her medical expenses under the consent to participate in the HERO study she signed, which states that Abbott agrees to pay reasonable medical expenses if, in Abbott's judgment, the injury was a direct result of the study. Am. Compl. ¶ 32. However, neither the Amended Complaint nor Plaintiff's opposition alleges that Abbott ever declined a demand to pay Plaintiff's medical expenses, so Plaintiff has not alleged breach. *See generally* Am. Compl., Opp. Even if she had, there would be no breach unless Abbott determined that the injuries were a result of the study. Am. Compl. ¶ 32. Plaintiff has not alleged that Abbott made such a determination. Plaintiff's breach of contract claim should therefore be dismissed for failure state a plausible claim on which relief can be granted under Rule 12(b)(6). *See Iqbal*, 129 S.Ct. at 1950.

[11] *See also Schakosky v. Client Servs., Inc.*, 634 F. Supp. 2d 732, 736 (E.D. Tex. 2007) (dismissing "agency-theory based claims" where plaintiff alleged no facts to demonstrate express control or apparent authority . . . .").

IV. Plaintiff's Allegations That Abbott's Attorneys Breached a Duty of Candor Are Incorrect and Provide No Basis For Denying the Motion to Dismiss.

Plaintiff opens her brief with the charge that Abbott has breached the duty of candor to this Court by failing to alert the Court to motions to dismiss it filed in unrelated cases in other jurisdictions. Plaintiff asserts that it is "more than a wee bit troubling" that Abbott did not bring to the Court's attention the fact that motions to dismiss filed by Abbott in other cases were denied, claiming—without citation to authority—that "the duty of 'candor with the Court' would, at minimum, require a citation." Opp. at 1-2 n.1. Presumably, Plaintiff is referring to Texas Disciplinary Rule of Professional Conduct 3.03, "Candor Toward the Tribunal," which applies in this Court. *See* S.D. Tex. L.R. 1(A). The duty of candor prohibits the attorney from "knowingly . . . fail[ing] to disclose to the tribunal ***authority in the controlling jurisdiction*** known to the lawyer ***to be directly adverse*** to the position of the client[.]" Rule 3.30(a)(4). Since "the decision of a district court in a foreign circuit is certainly not binding on this Court," *LaFarge Corp. v. Campbell*, 813 F. Supp. 501, 511 (W.D. Tex 1993), the argument that Abbott had a duty to bring the out-of-state decisions in question to the attention of this Court is specious.

Moreover, none of the previous motions addressed the central issue here—i.e., whether Texas's broad statutory proscription against products liability for manufacturers of FDA-approved drugs requires dismissal. Indeed, when the *Murthy* case was previously pending in Massachusetts state court, Abbott moved to dismiss based, among other things, on the operation of Section 82.007. Plaintiff's attorneys did not dispute that Section 82.007 would bar the claims, but instead argued that Texas substantive law did not apply to the lawsuit—a claim that Plaintiff's current lawyers have appropriately abandoned. *See* Opp. at 8.

Finally, Plaintiff's representation that Abbott has "lost every 'single motion to dismiss plaintiff's complaint'" it filed (Opp. at 1) is incorrect. To the contrary, Abbott has won at least

[12] Thus, the record of prior motions to dismiss Humira complaints, to the extent relevant at all, is mixed. In ***this*** case, Abbott appropriately and respectfully requests that this Court evaluate this Plaintiff's complaint on the merits, particularly with regard to the impact of Section 82.007.

CONCLUSION

For these reasons and the reasons discussed in Defendant Abbott Laboratories' Motion to Dismiss, Plaintiff's Amended Complaint should be dismissed with prejudice.

DATED: May 23, 2011

Respectfully submitted,

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[12] In a case pending in the Northern District of California, Judge Wilken granted Abbott's first motion to dismiss, dismissing all twelve of plaintiffs' claims against Abbott. *See* Order on Mot. to Dismiss, *Wendell v. Johnson & Johnson, et al.*, No. C 09-04124 CW, 2010 WL 271423 (N.D. Cal. Jan. 20, 2010) (Wilken, J.) (App. Tab 10). Judge Wilken granted the plaintiffs leave to amend, but when they did so, they realleged only their strict liability and negligence claims. *See* Bautista Decl., ¶ 4, Ex. A (First Am. Compl., filed on Feb. 9, 2010, *Wendell v. Johnson & Johnson, et al.*, No. C 09-04124 CW, N.D. Cal.).

Similarly, in a case in the Central District of Illinois, Judge Mills granted Abbotts' motion to dismiss all counts against it, finding that the complaint "alleged no specific facts which establish tortious conduct on [Abbott's] part" and requiring the plaintiff to plead the alleged facts with more particularity. *See Mohr v. Targeted Genetics, Inc.*, No. 09-3170, 2009 WL 4021153, at *3 (C.D. Ill. Nov. 18, 2009) (App. Tab 11). And although Judge Mills denied Abbott's subsequent motion to dismiss, he stated that plaintiff had alleged "just enough" facts and that dismissal was "a very close issue." *Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 718, 721 (C.D. Ill. 2010).

CERTIFICATE OF SERVICE

I hereby certify that on May 23, 2011, I electronically filed the foregoing document and the accompanying motion with the clerk of court for the U.S. District Court, Southern District of Texas, using the electronic case filing system of the court. The electronic case filing system sent a "Notice of Electronic Filing" to the following attorneys of record who are known "Filing Users":

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In addition, I served a copy of the foregoing document by U.S. mail at the addresses above.

/s/ *John R. Henderson*
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